No. 89-243

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF OF INDUSTRIAL BIOTECHNOLOGY ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

35 U.S.C. § 271(e)(1) provides that "[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*" (emphasis added).

The question presented is:

Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. § 271(e)(1) beyond "drugs" and "veterinary biological products" to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other federally-regulated, non-drug products?

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Industrial Biotechnology Association ("IBA") submits this brief *amicus curiae* in support of Petitioner Eli Lilly and Company. It is accompanied by written consents from Petitioner and Respondent.

INTEREST OF *AMICUS CURIAE*

In the past sixteen years, dramatic new developments in the ability to select and manipulate genetic material have sparked unprecedented interest in "biotechnology,"

or the industrial use of living organisms.[1] Current industrial applications of biotechnology include the production of new drugs, vaccines, medical devices, foods and food enzymes, chemicals and dyes, industrial enzymes, and biopesticides. Nonproduct-oriented commercial applications include the use of microorganisms to degrade toxic waste and forensic applications such as DNA fingerprinting.

As the diversity of applications suggests, biotechnology "could have a major impact on industries throughout the world." U.S. Congress, Office of Technology Assessment, *Commercial Biotechnology: An International Analysis*, at 3 (Washington, D.C.: U.S. Government Printing Office, January 1984).

Beginning around 1976, many small entrepreneurial firms were formed in the United States specifically to build on the growing body of fundamental knowledge in molecular biology and to profitably exploit it. Furthermore, large established companies in a spectrum of industrial sectors expanded their research and development programs to include the new genetic techniques. Today, several hundred entrepreneurial and established companies are dedicated primarily to developing products using biotechnology.

Combined, U.S. industry is spending an estimated $1.5 billion to $2.0 billion annually in biotechnology research and development. U.S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: U.S. Investment in Biotechnology*, at 5 (Washington, D.C.: U.S. Government Printing Office, July 1988).

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[1] "Biotechnology" includes "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific use." U.S. Congress, Office of Technology Assessment, *Commercial Biotechnology: An International Analysis* (Washington, DC: U.S. Government Printing Office, January 1984).

Amicus IBA is a trade association representing 82 large and small companies that use biotechnology to make new products. Collectively, its members represent a majority of the private sector investment made in biotechnology. IBA's member companies are listed in the appendix to this brief.

Many biotechnology companies are developing medical devices, especially the class of medical devices used to diagnose diseases and other biological conditions. According to the congressional Office of Technology Assessment, diagnostic tests are second only to human therapeutics as the area of primary research and development focus by biotechnology companies. *Id.* at 79. In addition, many of those that focus primarily on human therapeutics focus secondarily on medical diagnostics.

The primary targets of biotechnology research in the diagnostics field have been genetic and infectious diseases.[2] Advances in biotechnology-based diagnostics will afford improved and earlier detection of these diseases, leading to higher survival rates, reduced health care costs, and improved quality of life for patients. For example, the diagnostic tests used to protect our Nation's blood supply from the human immunodeficiency virus (HIV), which causes Acquired Immune Deficiency Syndrome (AIDS), are made using biotechnology. Other currently marketed biotechnology-based diagnostics include tests for detecting blood in the stool (an early warning of rectal cancer), tests for pregnancy and identifying the time of ovulation, and diagnostics for such diseases as ovarian cancer, cystic fibrosis, Huntington's disease, Duchenne muscular dystrophy, and hepatitis B. Clearly, it is critical to retain the incentives for producing important products such as these.

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[2] Genetic diseases are those in which heredity plays either an exclusive or significant role. Infectious diseases are spread from person to person through exposure to a virus or bacteria.

These medical products use known chemical compounds or biological substances which would be impossible or prohibitively expensive to make without biotechnological inventions. Each of these products owes its existence to the strong incentive to invest in research and development which patents offer. These patented biotechnological inventions are broadly applicable in medical device design, development and manufacture, and are often several steps removed from the product which is actually sold. For example, some diagnostic devices use monoclonal antibodies to detect minute amounts of hormones or disease antigens in the blood. These antibodies are made possible through biotechnological innovations in cell biology, tissue culture and manufacturing processes which precede the use of the antibodies themselves.

Under the Court of Appeals' decision, each issued patent offers in effect a short-cut for companies which have made no investment at all in pioneering research. In many cases, the biotechnology company has deposited essential biological materials in support of its patent application. These deposits, which are virtually unique to the biotechnology industry, will now become available to unlicensed companies not when the patent expires but as soon as the patent issues. The copier of a patented invention will be able to manufacture its generic product using these raw materials without compensating the patent holder. This places the otherwise-infringing company at an unfair advantage because its product uses materials which are not merely equivalent to the patented product, but derived from the same biological source.

The decision of the Court of Appeals may substantially erode patent rights and adversely impact the biotechnology industry. Thus, IBA's members have a compelling interest in having this Court correct the erroneous decision below and restore the full scope of patent protection for medical devices and other non-drug products.

SUMMARY OF ARGUMENT[3]

The decision of the United States Court of Appeals for the Federal Circuit interpreted a provision of the Drug Price Competition and Patent Term Restoration Act of 1984,[4] codified at 35 U.S.C. § 271(e)(1). It stated that the limited exemption from patent infringement under Section 271(e)(1) extends to medical devices, food additives, color additives, and other products regulated by the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act.

The plain language of Section 271(e)(1) makes clear that it applies only to the products specifically identified therein, *i.e.*, "drugs" and "veterinary biological products." The legislative history confirms this reading of the statute and unequivocally demonstrates that Congress intended the statute to apply only to drugs and veterinary biological products.

Nevertheless, the Court of Appeals inexplicably departs from both the plain words of the statute and Congress' expressed intent. Its misinterpretation of the statute belies its failure to recognize the important difference between drugs and non-drug products in their development and regulation. In expanding the limited scope of Section 271(e)(1), the Court seems to express its own policy choices instead of those of Congress. This judicial legislation is clearly improper. The decision below constitutes a serious error of law which should be corrected.

INTRODUCTION

This case presents a federal statutory question of potentially extensive adverse impact on innovation, research and development of federally-regulated products. Unless the Court of Appeals' decision is reversed, its

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[3] *Amicus* adopts the statement of the case set out in the brief of Petitioner Eli Lilly and Company.

[4] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

application will significantly erode the rights of patent holders in the medical device industry as well as in other industries in which biotechnology is being used.

For the first time, otherwise-infringing competitors will be able to make, use and sell patented inventions before the patent expires in order to obtain federal regulatory approval. This outcome, in effect, rewards copiers with an unfair advantage even though they did not undertake the substantial risk and enormous expenses required to research and develop the inventions. The Court of Appeals' misguided decision runs counter to the goals of the patent system, which is established to encourage the development of new inventions. Undoubtedly, it will reduce incentives for pioneering innovation, technological creativity and business investment, all of which are essential to the biotechnology industry.

IBA respectfully submits that the Court of Appeals' erroneous interpretation will have a far-reaching application beyond products regulated by the FDA, to agricultural chemicals and other patented, non-drug products that are subject to regulation by the federal government. The language of Section 271(e)(1) refers to ". . . uses reasonably related to the development and submission of information under *a Federal law* which regulates the manufacture, use, or sale of drugs or veterinary biological products" and thus may affect a broader range of products than medical devices (emphasis added).[5]

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[5] The Court of Appeals stated:

> Accordingly, we hold that Section 271(e)(1) allows a party to make, use, or sell *any type* of "patented invention" if "solely" for the restricted uses stated therein.

Eli Lilly and Co. v. Medtronic, Inc., 872 F.2d 402, 406 (Fed. Cir. 1989) (emphasis in original).

ARGUMENT

I. THE COURT OF APPEALS IGNORED THE PLAIN LANGUAGE OF THE STATUTE

This case raises traditional statutory interpretation issues. The relevant statute is a provision of the Drug Price Competition and Patent Term Restoration Act of 1984,[6] codified at 35 U.S.C. § 271(e)(1). It states:

> It shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products* (emphasis added).[7]

It is well-settled that "[the] starting point for interpreting a statute is the language of the statute itself." *Consumer Product Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980); *Mallard v. U.S. Dist. Court for Southern Dist. of Iowa*, 109 S.Ct. 1814, 1818 (1989) ("Interpretation of a statute must begin with the statute's language.") When the terms of a statute are unambiguous, courts must regard the statute as conclusive. *United States v. James*, 478 U.S. 597, 606 (1986). Assertions of ambiguity do not transform a clear statute into an ambiguous provision. *TVA v. Hill*, 437 U.S. 153, 173 n.18 (1978).

The language of Section 271(e)(1) is plain and clear. The straightforward reading of this statute is that it creates an exemption from the general patent infringement provisions of 35 U.S.C. § 271(a) for use of "drugs" and "veterinary biological products" in very limited situations. The Court of Appeals, however, inexplicably

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[6] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[7] The statute initially referred only to "a Federal law which regulates the manufacture, use, or sale of drugs." The term "or veterinary biological products" was added in 1988. Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988).

failed to effectuate this ordinary reading of the statute. Instead, it decided that the statute contained "ambiguous language" and used the excuse of nonexistent ambiguity to construe it to cover a wide range of non-drug products, including medical devices, food additives and color additives. This extraordinary conclusion is an outright distortion of the plain meaning of the statute.

The Court's interpretation of Section 271(e)(1) also departs from the reading of the statute by other courts as well as commentators. In the present case, the District Court and the Court of Appeals panel which denied Respondent's motion for a stay of the District Court's injunction read Section 271(e)(1) as limited to drugs. The only other court which has considered the matter reaches a similar conclusion. "[I]t is . . . clear that Section 271(e)(1) applies only to drugs, not to medical devices." *Scripps Clinic & Research Foundation v. Baxter Travenol Laboratories, Inc.*, 7 U.S.P.Q.2d 1562, 1565 (D. Del. 1988) (dictum).

Several commentators likewise agree that the statute "is limited to human drugs, and does not include medical devices, . . . food additives, color additives, or other related products." Flannery & Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 307-08 (1985). *See also* Fox & Bennett, *The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984*, at 178, 187 (1987).

II. THE LEGISLATIVE HISTORY CLEARLY EVIDENCES THE LIMITED, PRODUCT-SPECIFIC APPLICATION OF SECTION 271(e)(1)

In reaching its decision, the Court of Appeals violates another fundamental principle of statutory construction. If there is any doubt as to the meaning of a statute's language, courts must defer to the intent of

Congress. *See, e.g., Mackey v. Lanier Collections Agency & Service, Inc.*, 486 U.S. 825, 108 S.Ct. 2182, 2191 (1988). Just as it has misread the unambiguous words of the statute, the Court of Appeals has also misinterpreted Congress' expressed intent.

According to the Court, in enacting Section 271(e)(1), Congress intended to allow a party to make, use or sell any type of patented invention, provided the patented invention was used solely to develop information to submit to a federal regulatory agency. 872 F.2d at 406. IBA agrees with Petitioner that this holding is clearly a misinterpretation of the intent of Congress in enacting Section 271(e)(1).

A. In Enacting Section 271(e)(1), Congress Expressly Intended To Apply The Statute Only To Drugs

The intent of Congress to limit the infringement exemption solely to specifically-identified products is evident in the statute's language "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*" 35 U.S.C. § 271(e)(1) (emphasis added), as well as in its legislative history.

The background on the enactment of Section 271(e)(1) reveals that the purpose of the statute was to overrule the decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). In *Roche*, the Court of Appeals interpreted under Section 271(a) that it was an act of infringement to use a patented drug, prior to the patent's expiration, for purposes related to obtaining FDA approval for a generic substitute to be sold after the patent expires. The *Roche* court clearly indicated the issue was specifically limited to drug testing:

> The district court correctly recognized that *the issue in this case is narrow:* does the limited use of a pat-

> ented drug for testing and investigation strictly related to FDA approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable?

Roche, 733 F.2d at 861 (emphasis added).

Cognizant of this narrow holding of *Roche*, Congress indeed intended to restrict the infringement exemption under Section 271(e)(1) exclusively to drugs when it passed the statute in 1984:

> In Section 202, Congress would provide that it is not an infringement to make, use or sell a patented invention solely for uses reasonably related to the development and submission of information *for the purpose of obtaining FDA pre-marketing approval of a drug*. The purpose of the provision is to overturn the ruling in *Roche* . . . . That case held that Bolar infringed a patent owned by Roche when, during the patent term, Bolar used the patented substance to prepare a submission to the FDA for the purpose of enabling Bolar *to market the drug* after the patent expired.

H.R. Rep. No. 857, 98th Congress, 2d Sess., pt. 2, at 27, *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647, 2711 n.18 (emphasis added).

The legislative history expressly provides that "the *only activity* which [would] be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 8, *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647, 2692 (emphasis added). Other legislative commentary further evidences the congressional understanding that the *Roche* holding, and therefore the purpose of the legislation, was drug-specific:

> The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a *patented drug*

> *product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. Since the Committee's Subcommittee on Health and the Environment began consideration of this bill, the Court of Appeals for the Federal Circuit held that this type of experimentation is infringement.
>
> In *Roche* . . . the Court of Appeals for the Federal Circuit held that experimental use of *a drug product* prior to the expiration date of a patent claiming that *drug product* constitutes infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the *drug* after the patent expires.

Id. at 2678-2679 (emphasis added).

Yet, according to the Court of Appeals, Congress intended "to set aside the *Roche* interpretation of § 271(a) in all its ramifications" (872 F.2d at 406) and allow a party to make, use or sell any type of patented invention solely for experimenting and obtaining federal regulatory approval. There is simply no support for this interpretation.

This erroneous opinion evidences the Court's failure to properly review the legislative history of Section 271(e)(1) for guidance. While it correctly recognized that the statute was enacted to overrule the *Roche* decision, it failed to ascertain what Congress thought *Roche* meant and thus what Congress intended to overrule. Instead, the Court substituted its own interpretation of the meaning of *Roche*. In doing so, it completely ignored its own clear language in that case. As shown above, the Court specifically recognized in *Roche* that the case was limited to drugs. 733 F.2d at 861. Nothing in that decision supports the Court's conclusion that the *Roche* holding extended to all patented inventions subject to regulatory approval.

Also, it is noteworthy that the legislative history of Section 271(e)(1) is absolutely silent with respect to medical devices or other non-drug products. It offers no indication whatsoever that Section 271(e)(1) was intended to extend to these products. Given the far-reaching economic impact of such a sweeping change and Congress' concern with the constitutional ramifications of eroding patent rights,[8] it is implausible that Congress would have made the change without providing the affected industries an opportunity to state their case.

B. The Court Of Appeals Incorrectly Relies On The Legislative History Of Other Unrelated Provisions Of The 1984 Act

The Court's decision was apparently influenced by the fact that the 1984 Act, which included Section 271(e)(1), also provided for patent term restoration for drugs, medical devices, food additives and color additives. *See* 35 U.S.C. § 156. The Court concluded that the most logical reading of the 1984 Act was that Congress intended to apply Section 271(e)(1) to medical devices, and presumably also food additives and color additives, as well as drugs. 872 F.2d at 406. Clearly, there is no rationale to predicate the interpretation of Section 271(e)(1) upon the fortuitous happenstance that the Act, which grants a limited infringement exemption for drugs, also provides patent extension rights for drugs, medical devices and other FDA-regulated products. The patent term restoration provisions are entirely unrelated to the creation of the narrow infringement exemption for generic drug testing. The court's conclusion, unsupported by the legislative history, again demonstrates its erroneous approach to issues of statutory interpretation.

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[8] The legislative history shows that both generic and innovator drug manufacturers had extensive input in the drafting of Section 271(e)(1). *See, e.g.*, 130 Cong. Rec. H9123 (daily ed. Sept. 6, 1984) (statement of Rep. Gore).

"[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983). Congress expressed its intention clearly in the 1984 Act. When it intended to grant patent extension rights to certain inventions, it specifically identified them. *See, e.g.*, 35 U.S.C. § 156(f). In that statute, Congress expressly included drugs, veterinary biological products, medical devices, food additives, and color additives. By contrast, in Section 271(e)(1), Congress expressly identified only drugs and veterinary biological products. In accord with the *Russello* principle, the Court must give effect to this disparate inclusion and exclusion. In enacting the 1984 Act, Congress clearly intended some provisions to apply only to drugs and some to apply to drugs, medical devices, and other products.

C. The Subsequent Legislative History Of Section 271(e)(1) And Other Provisions Of 35 U.S.C. § 271(e) Confirm Congress' Intent To Limit Section 271(e)(1) To Specifically-Identified Products

Congress' intent to limit Section 271(e)(1) to specifically-identified products is further supported by its subsequent actions regarding the statute. In 1988, when Congress decided to add similar limited infringement exemptions to another category of patented product, *i.e.*, veterinary biological products, it did so by express amendment of Section 271(e)(1). *See* Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988).[9] This product-specific addition to Section

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[9] The legislative history of the 1988 amendment to Section 271(e)(1) further confirms Congress' intent to limit that statute to specifically-identified products, *i.e.*, drugs and veterinary biological products.

> This section amends Section 271 of Title 35 to provide that it is not an act of patent infringement to make or use an animal

271(e)(1) is irrefutable evidence that it was never Congress' intent in the 1984 Act (as amended in 1988) to include medical devices within the infringement exemption of that section.

Also, a review of other paragraphs of Section 271(e) confirms the product-specific application of Section 271(e)(1). When Congress created the limited infringement exemption for drugs, it provided offsetting protection for drug patent holders in the same section. 35 U.S.C. § 271(e)(2) establishes that it would be an act of infringement to submit new drug applications with the intention of obtaining marketing approval before patent expiration. 35 U.S.C. § 271(e)(4) sets forth remedies for such infringement. Congress granted similar protection to animal drug patent holders in the 1988 amendment to Section 271(e)(1). *See* 35 U.S.C. § 271(e)(2)(B). Thus, if Congress had intended to extend the application of Section 271(e)(1) to medical devices and other products, it is indeed illogical that Congress would have failed to confer the same protection on patent holders of those products. The fact that Sections 271(e)(2) and (e)(4) are clearly specific to "drugs" and "veterinary biological products" compels the conclusion that the related provision in 271(e)(1) is likewise specific only to drugs and veterinary biological products.

III. THE COURT OF APPEALS ENGAGED IN IMPROPER JUDICIAL LEGISLATION

As pointed out in the opinion of Circuit Judge Newman dissenting from the denial of a rehearing *in banc*, the Court of Appeals was legislating "without regard to the consequences for research and innovation or the public interest." *Eli Lilly and Co. v. Medtronic, Inc.*,

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drug or veterinary biological for purposes reasonably related to developing information for a submission to FDA. *A similar provision applies to human pharmaceuticals.*

S. Rep. No. 448, 99th Cong., 2d Sess. 13 (1986) (emphasis added).

879 F.2d 849, 850 (Fed. Cir. 1989) (Newman, J., dissenting). Judge Newman observed that Congress, not the Court, is empowered to legislate. *Id.* at 851 (citing *Fedorenko v. United States*, 449 U.S. 490, 514 n.35 (1981) and *Hobbs v. McLean*, 117 U.S. 567, 579 (1886)). By relying on its erroneous reading of the statute and congressional intent, the Court has engaged in improper legislation in the guise of statutory interpretation. The judicial function, however, is to apply statutes "on the basis of what Congress has written, not what Congress might have written." *United States v. Great Northern Ry. Co.*, 343 U.S. 562, 575 (1952). The Court may not substitute its policy choices for those of Congress and rewrite the law. *See, e.g., United States v. Rutherford*, 442 U.S. 544, 555 (1979) ("Under our constitutional framework, federal courts do not sit as councils of revision, empowered to write legislation in accord with their own conceptions of prudent public policy."). Nevertheless, the Court here seems to express its own view of applicable policy considerations. 872 F.2d at 406. Because of the wide range of products apparently now falling within the scope of Section 271(e)(1), the Court's decision will trigger a sweeping change in the patent law, which should properly be left to Congress.

IV. FUNDAMENTAL DIFFERENCES BETWEEN DRUGS AND NON-DRUG PRODUCTS PROVIDE PERSUASIVE REASONS FOR LIMITING THE INFRINGEMENT EXEMPTION TO DRUGS

In enacting Section 271(e)(1), Congress considered the constitutional ramifications of creating an exception to patent infringement. It was concerned with whether the law so eroded the exclusive rights of drug patent holders that it might result in an unconstitutional taking. After carefully reviewing those constitutional ramifications in the narrow context of bioequivalency testing, Congress concluded that the nature of the

interference was minimal.[10] H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 30, *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647, 2692. This focus on the limited nature of drug testing demonstrates Congress' recognition of the fundamental difference between drugs and non-drug products in their development and regulation. This case is a good illustration of the significant ways in which drugs differ from medical devices with respect to FDA testing.

To obtain FDA premarket approval, manufacturers of new drugs (both innovator and generic drugs) must submit data and information relating to the safety and effectiveness of the drug. See 21 U.S.C. § 355. Prior to 1984, there was no statutory provision pertaining to the requirements for gaining FDA approval of generic drugs. In Title I of the Drug Price Competition and Patent Term Restoration Act of 1984, Congress amended the drug approval statute to allow approval of generic drugs on the basis of "bioequivalency" tests rather than the full clinical trials otherwise necessary for FDA approval of innovator drugs. *See* 21 U.S.C. § 355(j).

Under this procedure, the manufacturer of a generic drug is not required to conduct independent clinical tests. Instead, it need show only that the rate and extent of absorption of its product is equivalent to that of the innovator drug. *See* 21 U.S.C. § 355(j)(7) (defi-

[10] The pioneering biotechnology industry does not agree with this characterization of the loss of patent protection. In fact, during congressional hearings on the issue, the research-based pharmaceutical industry submitted arguments that legislative reversal of the *Roche* decision would constitute an unconstitutional taking of property in violation of the Fifth Amendment to the United States Constitution. *Innovation and Patent Law Reform: Hearings on H.R. 3285, H.R. 3286, and H.R. 3605 Before the Subcommittee on Courts, Civil Liberties and the Administration of Justice of the House Committee on the Judiciary*, 98th Cong., 2d Sess. 516-522, 741-753 (1984) (Statement of Norman Dorsen and Memorandum of Laurence H. Tribe).

nition of bioequivalency). Since the bioequivalency tests are typically performed in the generic drug manufacturer's laboratories with a limited number of healthy volunteers who are not charged for the drug,[11] this type of abbreviated testing does not involve sales of the infringing drug and therefore does not take potential customers away from the patented drug manufacturer during the life of the patent. As a result, Section 271(e)(1) does not affect the ability of the manufacturer of a patented drug to command exclusive sales during the life of the patent.

There are no statutory abbreviated procedures available for establishing the safety and effectiveness of copies of innovator medical devices which have been required to undergo premarket testing[12] as there are for generic drug products. The "Abbreviated New Drug Application" provisions of Title I of the 1984 Act are undisputably applicable only to drugs and not medical devices. Clearly, Section 271(e)(1) must also be applicable only to drugs because these provisions are interrelated.

In contrast to drug testing, testing of non-drug products is not as well-defined or as simple. For example, to obtain FDA-required data, medical devices must be tested in a treatment setting. Development of data may, with respect to the more sophisticated devices such as CAT-scans, require purchases of the devices by medical institutions during the experimental stage. For other devices such as hip prostheses, clinical testing involves permanent implantation. Medical devices by and large cost much more than drugs.

[11] Volunteers who are ill will generally be used in bioequivalency tests for toxic drugs such as cancer drugs.

[12] Not all medical devices must undergo premarket testing. In 1976, Congress enacted a complex statutory scheme that includes differing types of regulation of medical devices based on their potential risks. *See* 21 U.S.C. § 360c *et seq.*

In this case, to conduct its investigational testing, Respondent marketed its generic medical device to be permanently implanted in patients, directly competing with the patent holder for potential customers during the period of the patent. Thus, unlike the bioequivalency testing of drugs, clinical testing of medical devices involves substantial sales of the device being tested and has significantly greater financial implications during the term of the patent.

These fundamental differences in testing procedures and approval requirements provide a persuasive reason for distinguishing between drugs and other patented inventions in Section 271(e)(1). Unfortunately, the Court below failed to recognize this critical difference, declaring that "[n]o persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation." 872 F.2d at 406.

Under the Court of Appeals' interpretation of Section 271(e)(1), it is permissible to market an otherwise-infringing product as long as the marketing is for the sole purpose of developing clinical data necessary for regulatory approval. The very nature of medical devices and the market structure of the relevant industries make this interpretation particularly damaging to the innovators of those devices. By misreading the statute and legislative intent, the Court of Appeals seriously undercuts the value of patents. It effectively reduces patent terms and may in some instances nullify patent protection altogether. This clear error of law will have an adverse impact on individuals and companies who innovate, develop and market inventions, particularly medical devices, and ultimately on those who would use and benefit from such inventions.

CONCLUSION

For the foregoing reasons, the decision of the Court of Appeals for the Federal Circuit should be reversed.

Respectfully submitted,

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November 22, 1989

APPENDIX

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November, 1989

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AMGEN
Thousand Oaks, California

AMOCO CORPORATION
Naperville, Illinois

ANAQUEST
Division of BOC
Murray Hill, New Jersey

APPLIED BIOSYSTEMS, INC.
Foster City, California

BAXTER TRAVENOL LABORATORIES, INC.
Deerfield, Illinois

BIOGEN INC.
Cambridge, Massachusetts

BIOSOURCE GENETICS CORPORATION
Vacaville, California

BIOTECHNICA INTERNATIONAL, INC.
Cambridge, Massachusetts

BRITISH BIC TECHNOLOGY LIMITED
Cowley, Oxford
England

CALGENE, INC.
Davis, California

CALIFORNIA BIOTECHNOLOGY INC.
Mountain View, California

CARGILL HYBRID SEEDS
Aurora, Illinois

CELGENE CORPORATION
Warren, New Jersey

CENTOCOR, INC.
Malvern, Pennsylvania

CETUS CORPORATION
Emeryville, California

CHEMAP, INC.
South Plainfield, New Jersey

CHIRON CORPORATION
Emeryville, California

CIBA-GEIGY CORPORATION
Greensboro, North Carolina

CODON
S. San Francisco, California

COLGATE-PALMOLIVE COMPANY
New York, New York

COLLAGEN CORPORATION
Palo Alto, California

CONNAUGHT LABORATORIES, INC.
Swiftwater, Pennsylvania

COORS BIOTECH PRODUCTS COMPANY
Westminster, Colorado

CROP GENETICS INTERNATIONAL
Hanover, Maryland

CYTOGEN CORPORATION
Princeton, New Jersey

DNA PLANT TECHNOLOGY CORPORATION
Cinnaminson, New Jersey

DNX
Princeton, New Jersey

THE DOW CHEMICAL COMPANY
Midland, Michigan

E.I. du PONT de NEMOURS & COMPANY
Wilmington, Delaware

EASTMAN KODAK COMPANY
Rochester, New York

ECOGEN INC.
Langhorne, Pennsylvania

ELI LILLY AND COMPANY
Indianapolis, Indiana

ENZYTECH, INC.
Cambridge, Massachusetts

GENENTECH, INC.
S. San Francisco, California

GENETICS INSTITUTE, INC.
Cambridge, Massachusetts

GENEX CORPORATION
Gaithersburg, Maryland

GENSIA PHARMACEUTICALS, INC.
San Diego, California

GENZYME CORPORATION
Boston, Massachusetts

GIST-BROCADES INC.
Charlotte, North Carolina

GLAXO INC.
Research Triangle Park, North Carolina

W.R. GRACE & COMPANY
Columbia, Maryland

GRANADA BIOSCIENCES, INC.
Houston, Texas

HAZLETON BIOLOGICS, INC.
Herndon, Virginia

HOFFMANN-LA ROCHE INC.
Nutley, New Jersey

HOUSTON BIOTECHNOLOGY INC.
The Woodlands, Texas

IBF BIOTECHNICS, INC.
Savage, Maryland

IMMUNEX CORPORATION
Seattle, Washington

IMPERIAL CHEMICAL INDUSTRIES PLC
Millbank, London
England

INVITRON CORPORATION
St. Louis, Missouri

LIFECODES CORPORATION
Elmsford, New York

LUBRIZOL ENTERPRISES, INC.
Wickliffe, Ohio

MERCK AND COMPANY, INC.
Rahway, New Jersey

MICROBIOLOGICAL ASSOCIATES, INC.
Rockville, Maryland

MILES INC.
Elkhart, Indiana

MONSANTO COMPANY
St. Louis, Missouri

MYCOGEN CORPORATION
San Diego, California

RJR NABISCO, INC.
Winston-Salem, North Carolina

NOVO INDUSTRI OF NORTH AMERICA, INC.
New York, New York

ORTHO PHARMACEUTICAL CORPORATION
Raritan, New Jersey

PARKE-DAVIS
Pharmaceutical Research Division
Warner-Lambert Company
Ann Arbor, Michigan

PHILLIPS PETROLEUM COMPANY
Bartlesville, Oklahoma

THE PILLSBURY COMPANY
Minneapolis, Minnesota

PIONEER HI-BRED INTERNATIONAL, INC.
Des Moines, Iowa

THE PLANT CELL RESEARCH INSTITUTE, INC.
Dublin, California

PORTON PRODUCTS
Washington, D.C.

THE PROCTER & GAMBLE COMPANY
Cincinnati, Ohio

REPLIGEN CORPORATION
Cambridge, Massachusetts

SANDOZ PHARMACEUTICALS CORPORATION
East Hanover, New Jersey

SCHERING-PLOUGH CORPORATION
Madison, New Jersey

G.D. SEARLE & COMPANY
Skokie, Illinois

SEPRACOR INC.
Marlborough, Massachusetts

SERONO LABORATORIES, INC.
Norwell, Massachusetts

SMITHKLINE BEECHAM
Philadelphia, Pennsylvania

E.R. SQUIBB & SONS, INC.
Princeton, New Jersey

T CELL SCIENCES, INC.
Cambridge, Massachusetts

TRANSGENE
Paris
France

TRANSGENIC SCIENCES, INC.
Worcester, Massachusetts

TRITON BIOSCIENCES INC.
Alameda, California

THE UPJOHN COMPANY
Kalamazoo, Michigan

VIAGENE, INC.
San Diego, California

WYETH-AYERST RESEARCH
Radnor, Pennsylvania